

### REMARKS

This Response is submitted in response to the Office Action mailed on May 19, 2003.

Claims 9-26 are pending. The Office Action rejects Claims 9, 10, 12, 18, 19 and 21 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In addition, Claims 9-11, 14, 17-20 and 24 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,639,368 ("*Niazi*"). Claims 9-26 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Niazi*. In response, Claims 9, 10, 12, 18, 19 and 21 have been amended. Applicants respectfully submit that all of the above-mentioned rejections have been overcome or are improper for reasons set forth below.

Claims 9, 10, 12, 18, 19 and 21 stand rejected under 35 U.S.C. § 112, second paragraph. In response, these claims have been amended to correct some of the informalities cited by the Examiner. These amendments have been made for clarification purposes and do not affect the scope of the claims in any manner.\* Applicants note for the record that they do not intend to disclaim any claimed subject matter via the amendment.

The present invention provides a coated chewing gum composition including a gum center. A coating substantially surrounds the gum center, the coating comprises at least 50% by weight of the chewing gum product. The coating includes a medicament or agent that is designed to be delivered into the systemic system of a patient. The present invention further provides a product including a medicament that is designed to function by being delivered through the systemic system of an individual. The product comprises a chewing gum center and a coating that substantially surrounds the chewing gum center and includes a medicament and a high-intensity sweetener. The coating comprises at least 50% by weight of the product.

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\* Applicants cannot understand the Examiner's objection to the word "including." In this regard, Applicants note for the record that the Patent Office's own internal guidelines state that "including" is synonymous with "comprising." See MPEP 2111.03.

Claims 9-11, 14, 17-20 and 24 are rejected under 35 U.S.C. § 102(b) as being anticipated by *Niazi*. Applicants submit this rejection is in error.

*Niazi* discloses a chewing gum composition that includes a chewing gum base, an orally administrable medicament, and a carbon dioxide generator. See Col. 2, Lines 20-25. *Niazi* further discloses that the chewing gum may also comprise a taste-bud desensitizing composition. See Col. 2, Line 27. However, *Niazi* completely fails to disclose or suggest any chewing gum compositions that comprise a coating. *Niazi* similarly fails to disclose or suggest any chewing gum compositions in which the coating comprises at least 50% by weight of the product. In addition to not disclosing a coating over the chewing gum base, *Niazi* discloses that the medicament and the gum base should be mutually compatible so that the medicament can be incorporated into the gum. See Col. 2, lines 30-35. [This suggests the medicament is incorporated within the gum base] and not in a form surrounding the gum base. Furthermore, in each example, *Niazi* only teaches incorporation of a medicament into the gum base. See Col. 5, lines 51-60. *Niazi* never discloses that the medicament is incorporated anywhere but within the gum base.

The present invention provides a coated chewing gum composition wherein the coating comprises at least 50% by weight of the product. *Niazi* clearly does not disclose a coated chewing gum or a chewing gum wherein the coating comprises at least 50% by weight of the product, and is therefore distinct from the present invention. Moreover, the present invention provides a chewing gum composition wherein the coating includes a medicament. *Niazi* only discloses incorporating the medicament within the gum base. Because of at least these two fundamental distinctions, *Niazi* cannot anticipate the present invention.

Claims 9-26 are rejected under 35 U.S.C § 103(a) as being unpatentable over *Niazi*. Applicants traverse this rejection and request reconsideration of same.

As discussed previously, *Niazi* discloses a gum wherein the medicament is incorporated within the gum center. *Niazi* also discloses a gum wherein a flavoring agent and a taste-masking material are incorporated within the gum base.

The present invention provides a coated chewing gum wherein the flavoring or taste-masking agent are incorporated into the coating. Contrary to the Examiner's position, there is no motivation or suggestion within *Niazi* to incorporate a flavoring or taste-masking agent into a coating. Indeed, insofar as *Niazi* only teaches the incorporation of a flavoring or taste-masking agent into a chewing gum base, it clearly constitutes a teaching away from the instant invention which requires the flavoring or taste-masking agent be contained within the coating.

In ascertaining the appropriateness of a particular reference as the basis for a rejection under §103, a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983), *cert denied*, 469 U.S. 851 (1984). Accordingly, Applicants respectfully submit that this rejection has been overcome and request withdrawal of same.

For the foregoing reasons, Applicants respectfully request reconsideration of their patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

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